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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,330	03/26/2004	Stefan Vilsmeier	SCHWP0187USA	1366
7590 10/26/2009				
Don W. Bulson RENNER, OTTO, BOISSELLE & SKLAR, LLP Nineteenth Floor 1621 Euclid Avenue Cleveland, OH 44115-2191				
EXAMINER ROZANSKI, MICHAEL T				
ART UNIT 3768		PAPER NUMBER		
MAIL DATE 10/26/2009		DELIVERY MODE PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/811,330

Applicant(s)

VILSMEIER ET AL.

Examiner

MICHAEL T. ROZANSKI

Art Unit

3768

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-19 and 21-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-19 and 21-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3-19, and 21-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Krause et al (US 6,711,432).

Krause et al disclose devices and methods for implemented computer-assisted surgical procedures including acquiring two dimensional images 83. A “morphing” software program is used to alter, bend, or morph a selected template bone model 88 (i.e. generic model) in a way that causes the projections 84, 86 of the model 88 to more closely match the 2D images 83. Such matching comprises projecting a 3D model onto 2D detection data. The morphing software alters the 3D template bone model 88 in small iterations until the projections of the model 84, 86 match the images 83. This comprises adapting the projections of the generic model to information of the 2D detection data. The software may then alter (stretch, bend, etc.) the generic model 88 in such a way that the model 88 conforms to the adapted projections of the generic model 88 (col 7, lines 9-43; see figure 3). Krause et al disclose that the result of these

procedures is a surgical plan that may also calculate the positioning of one or more surgical tools or bone markers to be used during the procedure. This part of the plan gives information to the surgeon for performing the surgery (col 4, lines 48-58). Specifically, the software places markers 110 near a target location 102 on the 3D patient bone model 100, and the markers are used to register bone location during surgery and anchor various surgical guides (col 10, lines 25-45; see figure 4C). Therefore, Krause et al provides for at least these positions being 'assigned' to the 3D patient bone model 100.

Claims 1, 3-19, and 21-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Vilsmeier (US 7,194,295)

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Vilsmeier discloses a method for computer-assisted medical navigation and/or treatment planning wherein the current position of a patient or a part of a patient's body and the positions of medical treatment devices are detected by means of a position detection unit, and wherein the detected positional data are assigned to body structure data, in order to jointly use the body structure data in assignment with the positional

data, within the context of assisting the treatment, wherein body structure data are used which are obtained based on a generic model which has been adapted by linking it with patient-characteristic detection data (see Abstract). The generic model can be adapted using one or more methods described in col 3, lines 40-53. Specifically, the adapting of the generic model may include offsetting points and landmarks or by shifting, rotating, stretching or compressing the generic model. This comprises adapting the projection of the model onto the patient-specific data using knowledge of the 3D, model-specific interdependence between anatomical landmarks and structures (similar to Applicant's specification para [0032]).

Response to Arguments

Applicant's arguments filed 8/25/09 have been fully considered but they are not persuasive. Applicant argues that Krause does not disclose detecting a position of a patient with the patient being in position for treatment and, without removing the patient from the position for treatment, acquiring patient-characteristic, 2D data. Examiner disagrees. First, it is noted that the software places markers 110 near a target location 102 on the 3D patient bone model 100 (i.e. patient-specific model), and the markers are used to register bone location during surgery and anchor various surgical guides (col 10, lines 25-45; see figure 4C). Therefore, Krause et al provides for at least these positions being 'assigned' to the 3D patient bone model 100. The software places the markers, which suggests that the position of the markers is detected, or determined. In regard to the position of treatment, it is unclear why the patient would not be in the

same position, as Applicant contends. As Examiner understands, the patient is in a treatment/surgery supine position during detection and image acquisition. While the reference notes that images are typically taken before surgery (col 6, line 46), this does not indicate that the patient changes position between detection and image acquisition. If this is not the case, Examiner requests that Applicant point out in Krause et al where the patient is removed from the treatment position.

In addition, it is noted that Krause et al teach that an IR marker system may be used during surgery, wherein the real-time IR sensing system tracks the markers and registers them to a pre-surgical 3D model. This provides feedback to the surgeon to guide the surgical procedure and allow greater accuracy in following the surgical plan (col 5, lines 16-25). Again, while detection takes place during surgery with the patient in the treatment position, the reference merely notes that images are taken before surgery. This doesn't indicate a change in patient position, but rather the images are acquired prior to surgery. Thus, the patient is in a supine position on a table during x-ray image acquisition and also in a supine position on a table.

In regard to Vilsmeier '295, Applicant argues that the projecting the 3D generic model onto the 2D detection data step is not met. However, Examiner disagrees. While not specifically using the term "projecting," Vilsmeier '295 appears to follow very closely in line with what Applicant describes in the specification (PG Pub version) in that the projection of landmarks is automatically or manually identified [0018], projection is adapted using knowledge of landmarks and structures [0032], and that the data set is displayed as a DRR by calculating the projection [0020]. Vilsmeier '295 discloses

acquiring landmark data and manually or automatically associating this data to the generic model, after which the model is adapted (col 3, lines 28-62). Here, it appears that the 'associating' includes a projection of landmarks of the 2D patient data to the generic model. Vilsmeier also disclose using DRR which appears to relate to a 2D data-3D model projection, wherein registering or fusing includes projecting. Furthermore, it appears that to adapt the model to conform to patient detection data (as Applicant has alluded to), that a projection between the model and detection data would occur. Without further defining and/or distinguishing from Vilsmeier '295, the claims will be interpreted in this manner.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL T. ROZANSKI whose telephone number is (571)272-1648. The examiner can normally be reached on Monday - Friday, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric F Winakur/
Primary Examiner, Art Unit 3768

MR